IeDEA Global Standard Operating Procedures (SOPs)

Principles and procedures for IeDEA multiregional research collaborations

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Administrative core and communications
Aimee Freeman
Johns Hopkins University
NA-ACCORD
afreeman@jhu.edu

Concept sheet management and output tracking
Morna Cornell and Kathleen Kehoe
University of Cape Town
IeDEA Southern Africa
morna.cornell@uct.ac.za; leenikehoe@gmail.com

Stephany Duda and Hilary Vansell
Harmonist
Vanderbilt University Medical Center
stephany.duda@vumc.org; harmonist@vumc.org

Global EC Chair
Annette Sohn
TREAT Asia/amfAR
IeDEA Asia-Pacific
annette.sohn@treatasia.org

These procedures outline the processes for proposing, engaging in, and disseminating results from research collaborations that involve the use of IeDEA multiregional data. *When proposed multiregional data use falls outside of these stated parameters, investigators are requested to contact the administrative contacts on page 1 for further clarification.*

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A. Background

The **International Epidemiology Databases to Evaluate AIDS (IeDEA)** is a global cohort consortium established in 2006 to develop seven regional data centers to gather, harmonize, and analyze data to address clinical and programmatic research questions in HIV/AIDS treatment and care (see www.iedea.org). This initiative is funded through 10 institutes, centers, and programs of the US National Institutes of Health (NIH): the National Institute of Allergy and Infectious Diseases (NIAID), the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), the National Cancer Institute (NCI), the National Institute of Mental Health (NIMH), the National Institute on Drug Abuse (NIDA), the National Heart, Lung, and Blood Institute (NHLBI), the National Institute on Alcohol Abuse and Alcoholism (NIAAA), the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), the Fogarty International Center (FIC), and the National Library of Medicine (NLM). The seven participating IeDEA regions (**Appendix 1**) are in Asia-Pacific (IeDEA Asia-Pacific), the Caribbean, Central and South America (CCASAnet), North America (NA-ACCORD), and sub-Saharan Africa (Central Africa IeDEA; East Africa IeDEA; IeDEA Southern Africa, IeDEA West Africa). In collaboration with participating sites, each region is responsible for the development of a regional research agenda, the establishment of mechanisms for receiving and combining data from sites, verifying the quality of these data, harmonizing definitions of variables captured, as well as for the implementation of methods for analyzing cohort data and training on data collection, processing and cleaning.

Multiregional research activities are an integral part of IeDEA. These include the identification of research questions to be addressed with combined data sets from multiple regions and other potential external research collaborators, the definition of key information to be obtained across regions, the development of protocols for hypothesis testing, data collection, coding, merging, harmonization, and data analyses. Multiregional research is primarily conducted through the development, execution, and completion of multiregional research concepts.

B. Roles and Responsibilities Within IeDEA Global for Managing Multiregional Research Activities

Coordination and improvement of concept management standards is guided by the **Concept Sheet Management and Output Tracking team** at the University of Cape Town (Leads: Morna Cornell, morna.cornell@uct.ac.za; Kathleen Kehoe, leenikehoe@gmail.com), the Data Harmonization Working Group (co-Chairs: Beverly Musick, bsmusick@iu.edu; Stephany Duda, stephany.duda@vumc.org), the Harmonist project (Lead: Stephany Duda, stephany.duda@vumc.org), and the EC Administrative Core team (Lead: Aimee Freeman, afreeman@jhu.edu), in collaboration with the below groups (**Figure 1**).

B.1 Regional data centers and sites

The IeDEA regional data centers (RDCs) are responsible for coordinating their region's participation in multiregional research collaborations through concept sheets or special projects (e.g., supplemental research, prospective cohort studies). Proposals for multiregional research in the form of analysis concept sheets or other documents are discussed in the context of relevant working groups, when appropriate, and formally submitted to the IeDEA Executive Committee (EC; see Section C.2) for consideration. Approval is at the EC level. The sites, according to regional procedures, will make their own decisions regarding participation in a given concept analysis or study.

Once a concept sheet or other research proposal is approved by the IeDEA EC and regional investigators, the RDCs' responsibilities include, but are not limited to, the following:

- Confirming which site(s) within their region will contribute data to individual research activities;
- Identifying regional representatives to act as point people for the research activities, as requested by concept or project leads;
- Ensuring that sites contributing data to the analysis/study have complied with associated regulatory and ethics requirements of their institution(s) and the NIH, and locally maintaining copies of regulatory approval documents on file;
- Circulating scientific products (e.g., abstracts, presentations, manuscripts) to their affiliated and data-contributing sites, according to regional policies and practices, for the purposes of review and approval.
- Supplying the requested data elements, associated reviews, and approvals in a timely manner.

B.2 IeDEA Executive Committee

The IeDEA EC is composed of the Principal Investigators (PI) of the seven IeDEA RDCs and representatives of the NIH funding institutes and centers (ICs). The EC oversees the multiregional agenda of the consortium, including multiregional projects and administrative coordination between both internal and external partners/collaborators. In addition to coordination, the EC has the responsibility to:

- Review and approve multiregional concepts and other proposals, and associated scientific products;
- Track progress of multiregional research activities;
- Moderate disagreements related to multiregional research activities between investigators.

The EC elects a Chair who serves in this capacity for a minimum of two years, who is supported by a core team from multiple regions (e.g., administration and communications at NA-ACCORD, concept and website management at IeDEA Southern Africa, investigator meetings at East Africa IeDEA) and by the Harmonist program. The EC meets by conference call on a monthly basis, and at an annual meeting. Meetings are coordinated by the Chair with support from the core team and NIH representatives.

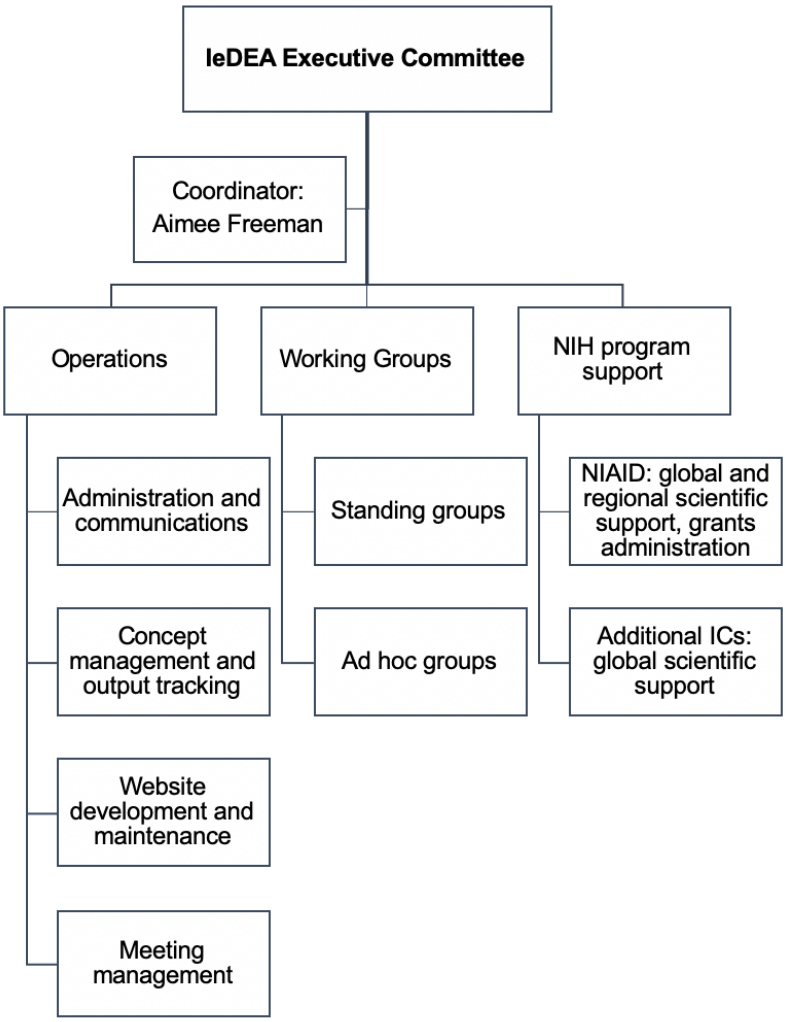
B.3 IeDEA Working Groups

There are multiple core Working Groups within the IeDEA consortium. They include:

- Adolescent and Young Adult Network of IeDEA (AYANI)
- Cancer
- Clinical Outcomes
- Data Harmonization
- Fogarty-IeDEA Mentorship Program – Coordinators (FIMP)
- Fogarty-IeDEA Mentorship Program – Trainees (FIMP)
- Hepatitis
- Mental Health
- Mother and Infant
- Pediatrics
- Sentinel Research Network (SRN)
- Site Assessment

- Substance Use
- Strategic Data
- Tuberculosis and Lung Health
- Tuberculosis Sentinel Research Network (TB-SRN)

Figure 1. IeDEA organizational chart



Each Working Group is chaired by IeDEA investigators who coordinate regular Working Group conference calls, annual in-person meetings, and develop IeDEA's scientific agenda around these topic areas. Working Group membership is generally limited to IeDEA investigators (e.g., representatives from participating research sites, coordinating centers, data management and analysis centers), other investigators directly affiliated with IeDEA regional research, and NIH program staff. Multiregional research concepts may be generated from within the Working Groups, or the EC or Working Group Chairs may ask one or more Working Groups to review a concept or scientific product of an analysis that includes their focus population (e.g., children, adolescents) or addresses their thematic area of interest (e.g., cancers). The Working Group review is intended to help assess feasibility and provide feedback for optimal design and

implementation of the analysis (see Section C.2). Additional ad-hoc Working Groups may be formed on a temporary basis for specific projects (e.g., Sentinel Research Network). Information on IeDEA Working Groups and their leadership is available at https://www.iedea.org/working-groups/

C. Management of multiregional research projects

Multiregional cohort database analyses will be managed through a concept-driven process. Concepts are required for research analyses and studies involving more than two of IeDEA's seven regions (i.e., three or more regions), regardless of study design (e.g., prospective cohort studies); concepts are optional for other IeDEA-related analyses and studies (i.e., involving two regions). Individual concepts for cohort database analyses and other studies will be reviewed and approved according to the below procedures and processes.

When proposed data use and research activities fall outside of the below parameters, investigators are requested to contact the EC Chair and administrative contacts for further clarification.

C.1 Management principles

A. Ownership of the regional cohort and other study-related data remains with the sites, as represented by the RDCs, led by the regional Principal Investigators (PIs).
B. Relevant concepts and protocols for multiregional cohort database analyses and other research projects must be reviewed and approved by the IeDEA EC in advance of any request for data.
    a. Additional *Working Group* reviews and approvals may be required, as appropriate (see below).
C. The review process seeks to ensure that proposed concepts and protocols are a) scientifically sound; b) methodologically viable; c) feasible within the limits of IeDEA global resources; and d) not duplicative of ongoing efforts.
D. All RDCs have one vote each on any concept proposal submitted to the EC for approval, regardless of whether or not they were invited to contribute data or will choose to participate in the research in the future. RDCs may formally abstain from voting.
E. An RDC can choose whether or not to contribute data (by individual sites or the entire region) to a multiregional cohort database analysis or other research project to which they were proposed to join.
F. Data transferred from one RDC to another data center or external partner for analysis of specific research concepts may only be used for that specific concept's analyses. Additional permissions from the EC and the participating RDCs are required for the use of the same dataset for a different concept.
G. Concepts initially approved for limited use (e.g., reporting to WHO, UNAIDS), must be revised and resubmitted for EC review should the concept leads want to proceed to develop a more complex analysis or a manuscript for publication.
H. **Only one manuscript may be produced for one multiregional research concept sheet ("one concept, one paper").** The development of additional manuscripts originating from a primary concept requires submission to the EC of a separate secondary concept for review and approval.
    a. Other multiregional research involving more than two IeDEA regions (e.g., supplemental studies, prospective cohort studies) are similarly subject to the "one concept, one paper" requirement.

I. Scientific products from multiregional concept analyses and other relevant research activities (e.g., abstracts, reports, manuscripts) require review and approval by the IeDEA EC before submission to a conference/workshop or journal, external presentation, or other form of distribution.
    a. A single concept may be associated with multiple abstracts.
    b. Posters and slide sets for oral presentations associated with previously approved abstracts should be reviewed by the EC and co-authors prior to presentation.
    c. Associated Working Groups are expected to review these products and presentations prior to or at the same time as the EC review.

C.2 Concept development and review steps

The process for concept development is outlined in **Figure 2**. Where there are questions about the concept management process, the narrative SOPs (this document) take precedence. Collaborations that involve more than two of IeDEA's seven regions (i.e., three or more regions) may be developed for the purposes of supplemental projects (e.g., hepatitis screening) or to answer limited research questions (e.g., focusing on outcomes in the Americas or across Africa). These projects should go through the standard review process as multiregional concepts

A. Concepts should be developed using the standard and current version of the IeDEA concept sheet template, available at https://www.iedea.org/resources/ (**Appendix 2**). Investigators are encouraged to work with regional data managers and the Data Harmonization Working Group during the concept drafting stage to facilitate the selection of variables that align with available multi-cohort data and application of the IeDEA Data Exchange Standard definitions, and to improve the efficiency of future data requests and transfer processes.
    a. Concepts associated with thematic or content-specific Working Groups (e.g., Pediatrics, Strategic Data) ***should be reviewed in their respective working groups prior to submission to the EC***.
    b. Concepts that involve new site surveys should also be reviewed by the Site Assessment Working Group (see section F).
B. When ready for EC review, the concept should be uploaded to the IeDEA EC Hub at **http://bit.ly/iedeasubmit**. Additional information about the concept is requested via the Hub "survey" tool that will be used when soliciting subsequent feedback.
C. The Hub administrators will review the submission for completeness and clarity. Once cleared, the proposed concept will be distributed for EC review through the Hub, along with supporting details provided via the Hub submission process. The EC will provide feedback, engage in discussion, and determine if the proposal is appropriate. ***A targeted end date for review, comment, and voting will be set for two calendar weeks after initial EC distribution***. Ideally, the concept will be presented on the next scheduled monthly EC conference call to allow for additional questions, clarifications, and discussion.
D. If approved, the Hub will send automatic notifications to the lead concept investigators and the IeDEA Concept Management Core at IeDEA Southern Africa (University of Cape Town IeDEA Project Manager [UCT PM in Figure 2]; Morna Cornell, morna.cornell@uct.ac.za), and Kathleen Kehoe, leenikehoe@gmail.com). The lead investigators will submit the final version of the approved concept on the Hub. The Concept Management Core will assign a tracking number, upload the final version to the Hub, and track the progress from concept approval to conclusion or publication.
E. Following or simultaneous to the EC review process, the regional PIs will distribute the concept to regional investigators for local decisions regarding participation, according to

internal regional policies and practices. Each regional cohort will decide through its own established procedures whether they will contribute data to the research and recommend cohort representative(s) to be part of the Writing Group for that concept. This should be done within ***four weeks*** of concept approval by the EC.

a. Specifically, the regional PIs are responsible to communicate to the lead concept investigators and their RDC data managers any additional details regarding regional approval and site/cohort participation that are needed for proceeding with the concept and associated data requests within ***four weeks*** of concept approval by the EC.

F. In the case of submission of concepts determined by the EC to require additional modifications before they can move forward (e.g., overlapping objectives, unclear analytical methods), these processes may take longer, pending additional discussions.

G. Concepts that need to be substantially amended or revised to reflect major additions or changes in scientific aims or how data will be used for that project should go through additional review processes, which may vary by concept (e.g., review by a working group, regional PIs, or full EC) and will be determined by the EC Chair and Administrative Core. Review deadlines will be adjusted, as appropriate.

a. The EC has the discretion to shorten the concept review timeline for amended/revised concepts if changes are minor.

H. **If plans for more than one manuscript develop from an approved concept, each subsequent manuscript will require a separate concept, which will need to go through each of the concept review steps *prior* to the initiation of these secondary analyses.**

C.3 Multiregional protocol reviews

Study protocols associated with other research involving more than two IeDEA regions should be reviewed by the EC prior to local and regional IRB submission, with sufficient time provided for substantive feedback and discussion. When these studies are led by IeDEA Working Groups (e.g., AYANI, SRN, TB-SRN), it is expected that the protocol development process will be the primary responsibility of those Working Groups. The process for initiating EC review of study protocols is similar to the one outlined for concepts in section C.2. Study protocols should be uploaded to the IeDEA EC Hub at **http://bit.ly/iedeasubmit** and select the “Other” category in the Hub upload submission form.

C.4 Data requests

Following EC +/- Working Group and regional-level cohort approvals, the concept leads will develop formal data transfer requests using standard tools and templates in accordance with the IeDEA Data Exchange Standard (contact the Harmonist team for details at harmonist@vumc.org).

A. If the data analysis is taking place ***outside of IeDEA***, additional steps may be required before transfer can occur (see Section D, Collaboration with external partners).

B. Concept leads are required to work with the Data Harmonization Working Group on the data specifications for their concepts.

C. *Requests for non-patient data.* IeDEA collects information about participating sites, clinical management practices, national guidelines, and other operational information. Use of such data would need to be requested and specified in a standard multiregional concept sheet. Once approved by the EC and data-contributing regions, these data can be requested through the EC operational core, which will forward them to the appropriate working group (e.g., Data Harmonization, Site Assessment, Strategic Data), as appropriate.

D. *Concepts not involving site- or patient-level data.* IeDEA working groups or investigators may work through the cohort consortium to develop concepts that do not require data per se (e.g., related to statistical methodology, the Data Exchange Standard). Such concepts may involve different types of internal approvals (e.g., by working groups and the EC, but not necessarily at the regional level) and authorship guidelines (e.g., authors outside of IeDEA and variable regional representation). It is advised that such concepts go through the standard review process to facilitate regional engagement and tracking, and avoid future confusion and overlap or duplication of effort.

C.5 Concept Writing Groups

A writing group will be assembled for each approved concept. Concept leads are encouraged to identify core members of their writing group soon after concept approval, in order to engage them earlier in the analysis and research product development processes (e.g., abstracts, reports, and manuscripts) and facilitate the receipt of regional-level feedback. Selection of writing group members and "masthead" co-authors representing an IeDEA region will be in compliance with regional authorship guidelines (see C.8).

A. The concept lead investigators who submitted the approved concept will be the point people for that group, unless otherwise specified. The group will generally include at least one investigator from each participating region.
B. Additional Writing Group members may be recommended by the lead investigators, the regional PIs and external collaborating cohorts, if appropriate.
C. The concept lead investigators have primary responsibility for completion of the analyses and preparation of related scientific products, as well as regular communications with the Concept Management Core, the relevant Working Group and EC Chairs, as appropriate.
D. The concept lead investigators are responsible for providing regular progress updates to other members of the Writing Group, relevant Working Group(s), the EC, and the Concept Management Core, and may be asked to provide updates directly to the EC.

C.6 Concept fast-track requests

In the event of a request for multiregional data or analysis outputs to inform model assumptions or for summary information for national or global reporting (e.g., by WHO, UNAIDS, national government partners), a fast-track process may be followed. The following criteria apply:

A. The request can be fulfilled through the use of an existing dataset that was created for a previously approved multiregional concept.
B. The RDC responsible for the existing dataset is willing and able to provide the requested information.
    a. Potential considerations for the data center may include additional time required to manipulate data or conduct new analytical work.
C. The request is for aggregated information, not individual-level data.
D. The IeDEA data or analysis outputs are not the primary focus of the model, report, or study, nor require IeDEA data or analysis outputs in order to be completed.
E. IeDEA will be acknowledged in an appropriate way for its contribution(s) (see below).

Requests meeting all of these criteria may be submitted by email to the IeDEA Administrative Core point person who will be responsible to process the request (see below). Requests should be provided in the IeDEA Fast-track Request template available at https://www.iedea.org/resources/ (**Appendix 3**) and include the following:

1) The title of the project
2) The names and affiliations of the investigators involved in the project
3) A brief description of the aims and purpose of the project (1 paragraph)

4) A description of the summary data or analysis outputs that are requested
5) An explanation of how these data will be used in the project
6) Expected future outputs (e.g., journal publication, policy document, model structure)
7) Confirmation that all of the above fast-track criteria have been met.

The request will be screened by the IeDEA EC Chair prior to circulation to the IeDEA EC for review on the Hub. The IeDEA EC will be given **one week** (inclusive of holidays, weekends) during which to raise any concerns. If the responsible data center(s) or the IeDEA regional PIs feel that the fast-track criteria are not met, they may recommend that a full concept sheet is submitted for further consideration.

IeDEA should be acknowledged for information provided through this fast-track process in a manner deemed appropriate by the data center(s) involved. If publication is anticipated, the data center(s) involved should review potential publications before these are published, and co-authorship may be explored.

Approved fast-track requests will be given tracking numbers by the Concept Management Core that are linked to the primary concept (e.g., “MR090-F1”).

C.7 Concept revisions

In the event that an approved concept needs to be modified in a way that does not require a separate fast-track request nor an additional separate concept, it may be submitted for EC review as a revision. The procedures for managing revisions are similar to those in C.2, except that proposed revisions should be submitted in tracked changes to the previously approved concept file.

Approved revision requests will be given tracking numbers by the Concept Management Core that are linked to the primary concept (e.g., “MR116-R1”).

C.8 Authorship

Authorship allocations by region and decisions about group authorship should be made prior to requests for review of research products (e.g., abstracts, reports, manuscripts), even if some co-authors are still to be named.

A. Authorship slots are generally distributed between the concept’s lead region and data-contributing regions. To the extent possible, the lead region should seek balanced representation across the participating regions. This may be based on levels of contribution to the analysis and abstract, the numbers of patients contributed to the analysis, and other factors.
    a. Authorship for the prospective SRN cohort study generally includes the same number of authors for each data-contributing region (e.g., n=2), with additional authors representing the concept leads (e.g., n=2). Other co-authors (e.g., content experts) may be added with the approval of the concept leads and the SRN Working Group.
B. For abstracts or manuscripts that have a restriction on the number of masthead authors, the priority authorship from within the Writing Group would be (1) investigators on the Writing Group working directly on the analysis and drafting the manuscript; (2) investigators on the Writing Group from among regions that contribute data; (3) other IeDEA representatives.
C. If the authorship restriction results in a total number of authors that is less than what the Writing Group deems reasonably representative, the masthead may include the concept

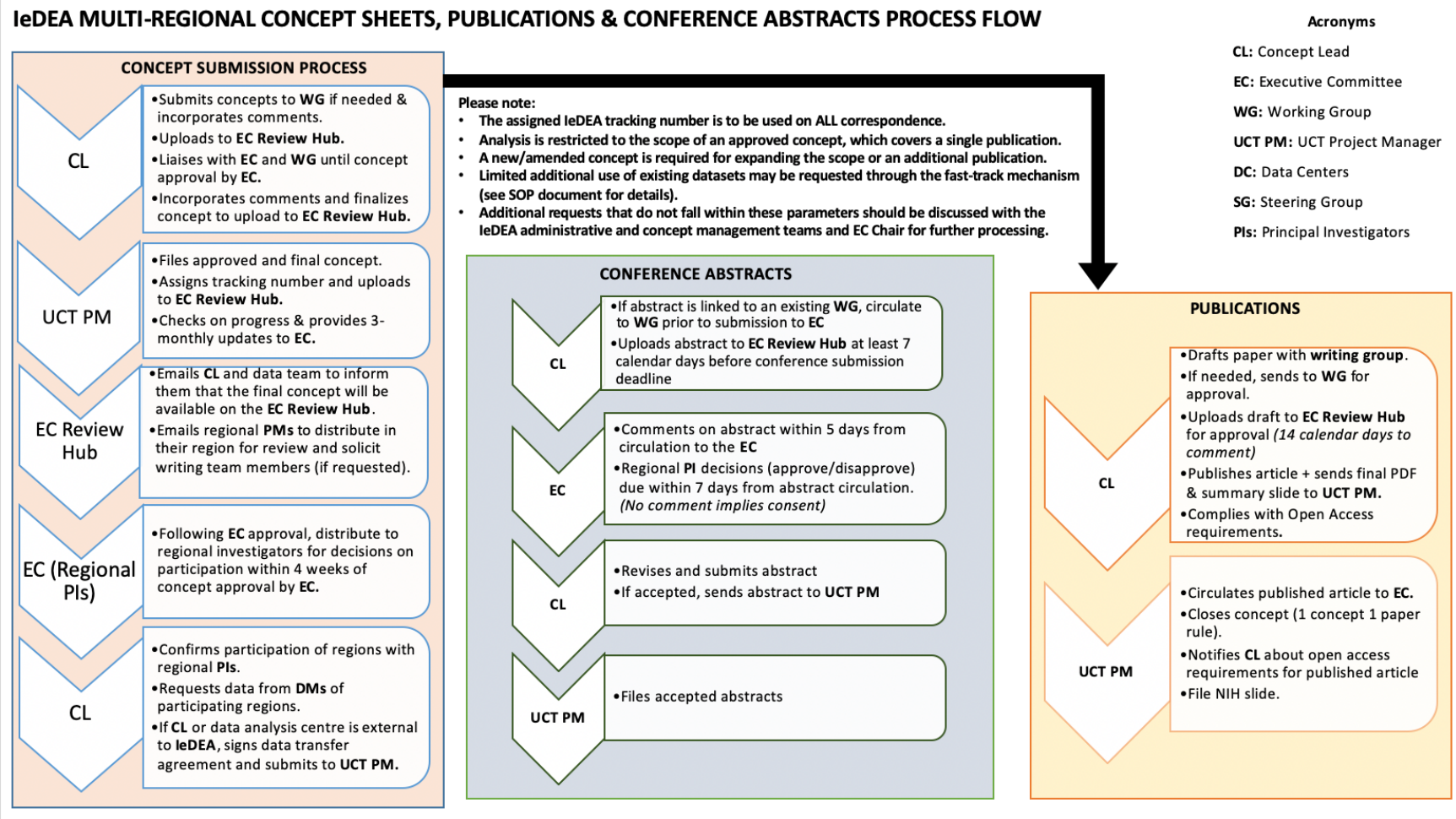
lead(s) and state “on behalf of IeDEA,” with the concept leads responsible for final selection of authors.

D. The inclusion of co-authors should be determined in line with the Uniform Requirements issued by the International Committee of Medical Journal Editors (see http://www.icmje.org/).
E. If the manuscript is published under group authorship, the Writing Group should be listed in the appendix and include all individuals who have made substantial contributions.
F. All multiregional abstracts, manuscripts, and reports regardless of restrictions on the numbers of masthead authors must have one authorship slot for the consortium, such as “…on behalf of IeDEA.”

C.9 Acknowledgement of regional investigators and funding

A. ***All IeDEA funding grants for all data-contributing regions must be acknowledged and listed in submitted and final published manuscripts.*** This may include the funding grant for the Harmonist program as well. The most up to date version of the IeDEA global and regional acknowledgements is available at https://www.iedea.org/resources/.
B. Depending on the manuscript and the scope of the collaboration (e.g., within or beyond IeDEA), investigator lists (e.g., steering or project committees) characterizing the leadership of the individual participating regions would be included in the acknowledgements or an appendix (**Appendix 4**).

Figure 2


IeDEA MULTI-REGIONAL CONCEPT SHEETS, PUBLICATIONS & CONFERENCE ABSTRACTS PROCESS FLOW
CONCEPT SUBMISSION PROCESS
CL
•Submits concepts to WG if needed & incorporates comments.
•Uploads to EC Review Hub.
•Liaises with EC and WG until concept approval by EC.
•Incorporates comments and finalizes concept to upload to EC Review Hub.
UCT PM
•Files approved and final concept.
•Assigns tracking number and uploads to EC Review Hub.
•Checks on progress & provides 3-monthly updates to EC.
EC Review Hub
•Emails CL and data team to inform them that the final concept will be available on the EC Review Hub.
•Emails regional PMs to distribute in their region for review and solicit writing team members (if requested).
EC (Regional PIs)
•Following EC approval, distribute to regional investigators for decisions on participation within 4 weeks of concept approval by EC.
CL
•Confirms participation of regions with regional PIs.
•Requests data from DMs of participating regions.
•If CL or data analysis centre is external to IeDEA, signs data transfer agreement and submits to UCT PM.
Please note:
The assigned IeDEA tracking number is to be used on ALL correspondence.
Analysis is restricted to the scope of an approved concept, which covers a single publication.
A new/amended concept is required for expanding the scope or an additional publication.
Limited additional use of existing datasets may be requested through the fast-track mechanism (see SOP document for details).
Additional requests that do not fall within these parameters should be discussed with the IeDEA administrative and concept management teams and EC Chair for further processing.
CONFERENCE ABSTRACTS
CL
•If abstract is linked to an existing WG, circulate to WG prior to submission to EC
•Uploads abstract to EC Review Hub at least 7 calendar days before conference submission deadline
EC
•Comments on abstract within 5 days from circulation to the EC
•Regional PI decisions (approve/disapprove) due within 7 days from abstract circulation. (No comment implies consent)
CL
•Revises and submits abstract
•If accepted, sends abstract to UCT PM
UCT PM
•Files accepted abstracts
PUBLICATIONS
CL
•Drafts paper with writing group.
•If needed, sends to WG for approval.
•Uploads draft to EC Review Hub for approval (14 calendar days to comment)
•Publishes article + sends final PDF & summary slide to UCT PM.
•Complies with Open Access requirements.
UCT PM
•Circulates published article to EC.
•Closes concept (1 concept 1 paper rule).
•Notifies CL about open access requirements for published article
•File NIH slide.
Acronyms
CL: Concept Lead
EC: Executive Committee
WG: Working Group
UCT PM: UCT Project Manager
DC: Data Centers
SG: Steering Group
PIs: Principal Investigators

D. Collaboration with External Partners

IeDEA regions or Working Groups may be asked by external groups (e.g., WHO, UNAIDS) or individuals to contribute data or pre-analyzed results to an analysis, a report, or a manuscript outside the context of an existing multiregional research concept. While individual RDCs will independently manage requests limited to their region, when estimates or data from more than two IeDEA regions are involved, the proposed project must be presented in advance to the IeDEA EC for their consideration and to determine if a multiregional research concept should be developed. This process may involve additional preliminary discussions with sub-groups of IeDEA investigators and NIH IC representatives. The IeDEA Strategic Data Working Group will generally be designated to review these requests prior or simultaneous to review by the EC. Additional Working Groups may be asked to review, depending on the scope of the proposed research and complexity of the data request. All external projects must have a designated IeDEA liaison who is primarily responsible to assist the investigators outside of IeDEA to guide the project through IeDEA submission, review, and finalization processes.

Data transfers for analysis by partners outside of the seven IeDEA regions will require a data transfer agreement between each participating region and the external group. Where data are provided for inclusion in a report, and the lead author(s) subsequently wish to publish these results in a peer-reviewed journal, **a separate concept sheet must be submitted** and the usual approval process followed. As with internal analyses, any subsequent use of data contributed to an external collaboration **must be separately authorized by the EC and the regions** that contributed data.

E. IeDEA Review Processes for Multiregional Scientific Products

E.1 Overview

The concept lead investigators act as overall scientific leaders and manage the workflow from concept to publication. This includes providing regular updates to their co-authors, the relevant Working Groups, the IeDEA coordination teams (e.g., concept management, Harmonist, EC), and the EC, as appropriate. The process is tracked by the Concept Management Core and Harmonist team.

The concept lead investigators usually act as the first or senior author, and corresponding author on abstracts, reports, and manuscripts. They determine authorship order and distribution across participating regions in accordance with IeDEA authorship policies, ensure that accepted abstracts are presented at conferences and workshops, share draft documents and presentations for review, and adhere to other IeDEA policies and practices.

All scientific products must be reviewed at multiple stages of the development and finalization process. These products include and are not limited to data reports (e.g., for modeling inputs, infographics, online resources), conference abstracts, manuscripts and reports for publication (e.g., online, peer-reviewed journal), conference posters, and presentation slides. All products are to be reviewed by co-authors, associated Working Groups, and the EC (Figure 3).

After initial reviews and approvals by co-authors and associated Working Groups, scientific products are submitted to the EC for review and approval (**Figure 3**). Coordination of the review process is managed by the concept lead investigators for their co-authors, the Working Group Chair(s) for their members, and the EC Chair and the Administrative Core for the EC. Review periods will vary by research product (e.g., 7 days for fast-track concepts and abstracts, 14 days for standard concepts, manuscripts, reports).

The EC review utilizes the IeDEA EC Hub. After EC reviews, concept leads are responsible for making the revisions requested or explain why revisions were not done. All approvals must be unanimous, with the option to abstain. If no serious concerns are noted after the formal comment period, the EC Chair may proceed with approval after clarification by email. If EC approvals are deferred, the concept leads will work with the dissenting regional PIs in order to resolve the situation to achieve consensus. If regions choose to withdraw their data from a previously approved analysis, this should be discussed with the concept leads in advance to avoid undue delays or barriers to completion for the other regions.

Figure 3. Review and approval requirements for IeDEA multiregional scientific products

Item	**Co-authors**	**Working Group(s)**	**Executive Committee**	
	Review	Review	Review	Voting
Concept sheet (fast-track, standard)	X	X	X	X
Data product	X	X	X	X
Abstract	X	X	X	X
Manuscript	X	X	X	X
Report	X	X	X	X
Conference poster	X	X	X	Not required
Presentation slides	X	X	X	Not required

E.2 Abstracts

All abstracts for international, regional, and national meetings related to approved, multiregional IeDEA concepts require formal approval by the IeDEA EC prior to submission. Questions about these procedures can be discussed with the Administrative Core and EC Chair.

A. Abstracts should be submitted to the Hub for EC review. Abstract submission deadlines for EC distribution are based on US Eastern [Standard or Daylight] Time (e.g., 5pm US ET).
B. To have adequate time for regional review, concept leads must submit proposed abstracts to the IeDEA EC ***at least 7 calendar days prior to the conference abstract deadline. Individual conference-specific deadlines will be set by the Administrative Core and may take weekends or holidays into consideration***.
C. ***Substantive comments and concerns are due back to the concept lead investigators within 5 days and regional PI decisions (approve/disapprove/abstain) are due within 7 days after abstract circulation***.
D. Prior to submission, revisions requested by the EC should be incorporated or the concept leads should explain why they were not incorporated. Concept leads should upload final submitted versions of abstracts to the EC Hub.
E. Abstract submitters are encouraged to notify the Administrative Core in advance if they plan to submit an abstract to a given conference. This will improve communications, help regions to anticipate reviews, and ***may impact on whether the abstract is eligible for review*** (e.g., for workshops like IWHOD that have a per cohort abstract limit).

F. Working Group reviews: Abstracts arising from concepts developed through Working Groups should be reviewed and approved by the Working Group ***prior to EC review***. If this is not feasible, the relevant Working Group Chair(s) will determine whether simultaneous review by the Working Group(s) and the EC is appropriate.
G. Author reviews: ***Prior*** to submission on the Hub for EC review, draft abstracts must be reviewed by the Writing Group. Co-author lists and discussions about group authorship should be clarified as much as possible ***prior*** to circulation of the abstract to the EC.
    a. Specifically, abstracts will only be circulated for EC review if there is confirmed approval by at least one co-author (named or as part of group authorship) from every participating region. Even if additional regional co-authors are still to be confirmed at the time of EC circulation, all named co-authors and participating regions must approve the abstract prior to EC review.
    b. Additional criteria for EC review may be specified in advance for individual conferences/meetings (e.g., IWHOD for submission limits per cohort). Failure to confirm required authorship by EC-specified deadlines may result in non-circulation of the abstract or withdrawal following circulation (see E.2.H).
    c. Authorship slots are generally distributed between the concept's lead region(s) and data-contributing regions. The lead region should seek balanced representation across the participating regions (see C.8). This may be based on levels of contribution to the analysis and abstract, the numbers of patients contributed to the analysis, or other factors.
    d. All multiregional abstracts must have one authorship slot for the consortium, such as "…on behalf of IeDEA."
H. Abstract rejections by the EC: Abstracts may be rejected in the following situations: Late submission for review, failure to respond to substantive feedback, inability to achieve consensus on the authorship list, or unresolvable disagreement among regional PIs about the abstract. The EC Chair will manage discussions around abstract rejections.
    a. If only one region rejects the abstract, the concept leads have the option to reanalyze the data without that region's data and request re-review by the EC. This option will be discussed by the EC on a case-by-case basis and is subject to review timelines specified by the EC Chair. Abstracts that are rejected by two or more regions will not be submissible.
I. Accepted abstracts: Concept leads are responsible for sending the accepted abstract and presentation details to the Administrative Core and the Concept Management Core for tracking.

E.3 Manuscripts and reports

IeDEA investigators seeking to submit multiregional manuscripts to peer-reviewed journals (pre-prints and standard publication) or reports to external partner agencies require formal approval by the IeDEA EC ***prior*** to submission. Manuscripts must have ***already been reviewed and approved by the co-authors and appropriate Working Group(s)*** and have incorporated their feedback in advance of EC review. Simultaneous review by the associated Working Group may be considered with the approval of the Working Group Chair(s) and EC Chair. Questions about these procedures can be discussed with the Administrative Core and EC Chair.

A. Following other appropriate reviews and approvals, the lead investigator should send the manuscript or report files for EC review through the IeDEA Review Hub (see Section C.2 and **Appendix 2**).
    a. The decision to release a multiregional research manuscript as a pre-print prior to standard publication must be approved by all co-authors and data-contributing regions.
B. The EC will review and comment on the manuscript and associated files within ***14 calendar days,*** which may require further distribution at the regional level, as deemed

necessary by each region. Concept leads also have the option of circulating "early drafts" for EC feedback. Submission of "final draft" files for formal review will still be required at a later date prior to submission.

C. Request for revision: The EC may request that a revised manuscript or report be re-circulated for further review, prior to providing approval for formal submission to a journal or an external group/organization. Revisions requested by the EC should be incorporated or the concept lead should explain why they were not incorporated. Concept leads should upload revised documents to the same section of the IeDEA Review Hub where the original version is posted.
D. Revisions made during the process of a journal editorial review are at the discretion of the concept leads, Writing Group, and co-authors. Substantial changes to previously approved manuscripts may require additional Working Group and/or EC review.
E. Concept leads and the primary regional cohort leading the concept analysis for a given manuscript or report are responsible for ensuring full compliance with the US NIH's Public Access Policy. This includes ensuring that all grant support is included in submitted manuscripts or reports, and that publishing or copyright agreements are consistent with funder requirements to submit publications to PubMed Central (consult http://publicaccess.nih.gov/submit_process_journals.htm for detailed instructions).
F. Concept leads are responsible for sending a copy of the published article and a single slide summarizing the publication to the Concept Management Core.

E.4 Other scientific products

Concept leads can contact the EC Chair or EC Administrative Core for information on review procedures for other products.

F. IeDEA Review Processes for Multiregional Site Surveys and other site-level data collection

F.1 Overview

IeDEA undertakes periodic surveys among sites that are actively participating in the consortium. These site surveys range from the general IeDEA-wide Site Assessment, which is conducted every 2 to 3 years among active IeDEA sites, to focused surveys on specific patient populations (e.g., pediatrics, pregnant and lactating women, etc.) or areas pertaining to the delivery of specific services (e.g., treatment for mental health and/or substance use disorders, TB, cancers, etc.). Participation by all IeDEA regions in the IeDEA-wide Site Assessment is expected and stipulated by NIH in the IeDEA request for applications (RFA), but regions may choose to participate in additional site surveys to explore different questions that arise among IeDEA sites.

Site surveys may be developed through the Site Assessment Working Group or through any of the core Working Groups within the IeDEA consortium (see section B.3) for surveys targeting sites from more than two regions. Site surveys involving more than two regions require an associated multiregional concept proposal approved by the EC prior to being circulated to participating sites. This review process helps to minimize unnecessary duplication of efforts, limit burdensome, simultaneous requests of IeDEA sites, and help ensure that efforts expended on primary data collection yield high-quality data that is usable in multiregional analyses and publishable. The review process is coordinated by the Executive Committee (EC) Chair and the Administrative Core.

F.2 IeDEA-wide General Site Assessment Surveys

General site assessment surveys are developed by the Site Assessment Working Group (SAWG) to gather timely and relevant site level data using a concept driven approach, with

priority given to (1) ensuring the quality, accuracy, scientific integrity and utility of the data collected and (2) facilitating longitudinal analyses of the capacity and services provided at sites across the IeDEA network. For each general Site Assessment survey, an umbrella concept using the standard multiregional concept proposal template and final version of the site assessment questionnaire will be submitted for EC review. Linked concept proposals will be submitted for new survey content and/or content related to specialized services (e.g., TB, maternal and child health, mental health conditions, substance use disorders, etc.) provided to patients enrolled in HIV care. Standard multiregional concept review processes (see section C.2) will be followed. Key principles guiding the development of content for the general site assessment surveys include the below.

A. Giving priority to questions that cannot be answered through other means. Questions that can be addressed through other approaches (e.g., analyses of regional datasets to ascertain the numbers of patients in care or with specific comorbidities or policy and guideline reviews to ascertain standards of care) are discouraged. Site surveys should not endeavor to collect or have respondents estimate or aggregate patient-level or laboratory test data (e.g., proportion testing positive in a given month, etc.).
B. Giving priority to questions exploring capacity and service delivery attributes, as well as routine practices and implementation outcomes, rather than questions that explore clinical management protocols.
C. Giving priority to questions that can be readily and reliably addressed by general clinical personnel at IeDEA sites. Questions that are suited to staff at outside clinics not participating directly in IeDEA (e.g., antenatal care, oncology, tuberculosis clinic), community partners, or specialized cadres of staff at a site (e.g., data managers, mental health providers) are discouraged.
D. Following a concept-driven process for new survey content, ensuring that any new questions added to the survey are supported by concrete plans for analysis and publication.
E. Retaining some survey content from prior site surveys across iterations to facilitate longitudinal analyses of salient aspects of HIV care. Content from prior surveys is retired when it is no longer relevant in the context of prevailing practices and treatment recommendations for HIV care, when analyses of previously-collected data illuminate widespread data quality concerns and difficulties in interpretation, or when the data have not been used by IeDEA investigators.

F.3 Specialized Site Assessment Surveys

Specialized site assessment surveys may also be developed by any of the other core IeDEA Working Groups to explore areas of service delivery not covered by the general Site Assessment. Processes for the development, review, approval and implementation of such surveys include the below.

A. The IeDEA Working Group(s) will follow its standard processes for the development of the survey content, and will prepare a concept for the specialized survey, using the multiregional concept proposal template.
    a. Concept leads should include information on their sampling plan (e.g., countries and types of sites to be included, as well as sampling methodology, as applicable) and intended survey respondent (e.g., staff within the HIV clinic vs. other site staff).
    b. The IeDEA working group(s) and the investigators will be responsible for ensuring that the SAWG reviews the concept proposal.
B. Prior to approval by the associated IeDEA Working Group(s), the concept proposal, survey questionnaire and sampling plan will be shared with the SAWG for technical review from a survey design and measurement perspective.

a. Draft site surveys should include introductory language to orient respondents to the nature of the survey and give instructions for how to complete the survey (see Site Assessment 4.0 for example text).
b. The review by the SAWG will focus on ensuring that the proposed content (1) does not overlap with other recent (within 2 years) surveys; (2) yields data that is measured as accurately and as scientifically valid as possible; (3) will not be overly burdensome for regional data centers and/or IeDEA sites to complete; and (4) follows best practices for questionnaire design and electronic data capture.
c. The SAWG feedback and recommendations will be shared with the concept lead(s) and co-chairs of the associated IeDEA Working Group(s). If there are major concerns about survey design and/or measurement issues, the concept lead(s) may be requested to share a revised version with the SAWG prior to approval by the associated IeDEA working group(s) and submission to the EC.

C. The final concept proposal, including survey questionnaire and sampling plan will be submitted for EC review, according to IeDEA's standard concept review processes (see Section C.2 and **Appendix 2**).
    a. Regions may opt out of specialized surveys entirely or choose to distribute such surveys to a subset of their sites.
D. After approval by the EC, the final survey questionnaire in English (and other languages, where applicable), as well as draft survey response forms, if available, will be provided to SAWG colleagues based at Vanderbilt University Medical Center for programming. If an individual IeDEA region opts to lead their own survey implementation using REDCap or another platform, this may be discussed with the SAWG.
E. To reduce the burden of survey implementation on regional data centers and IeDEA sites, the content of multiple specialized surveys may be bundled together, with survey bundles fielded roughly every six months (e.g., June-July and December-January).
F. On behalf of the SAWG, Vanderbilt University Medical Center will generate unique survey links for each site when they are responsible for survey implementation, in accordance with the sampling plan, and will share those links with regional data centers, which will coordinate the implementation of the survey within their region. When individual IeDEA regions are responsible for survey implementation, this process will be planned in collaboration with the SAWG and Vanderbilt team.

F.4 Accessing data from IeDEA Site Assessment Surveys

Survey data from general and specialized site assessment surveys will be made available to IeDEA investigators by the Site Assessment Working Group or concept leads, based on an approved multiregional concept. In addition, with approval from regional PIs, IeDEA investigators may request access to data from any general or specialized survey for all sites within their respective IeDEA region. A list of past surveys can be accessed at: https://rocket.app.vumc.org/index.php?wg=ws4983

G. Appendices

1. IeDEA Global Regions and Principal Investigators

Asia-Pacific Annette Sohn amfAR TREAT Asia Bangkok, Thailand Matthew Law Kirby Institute University of New South Wales Sydney, Australia https://iedea-ap.org/	Australia Cambodia China and Hong Kong SAR India Indonesia Japan Malaysia Philippines Singapore South Korea Taiwan Thailand Vietnam
Caribbean, Central and South America (CCASAnet) Catherine McGowan and Stephany Duda Vanderbilt University Medical Center Nashville, Tennessee Pedro Cahn Fundación Huésped Buenos Aires, Argentina www.ccasanet.org	Argentina Brazil Chile Haiti Honduras Mexico Peru
The North American AIDS Cohort Collaboration on Research and Design (NA-ACCORD) Richard Moore and Keri Althoff Johns Hopkins University School of Medicine Baltimore, Maryland www.naaccord.org	Canada United States of America
Central Africa Kathryn Anastos and Marcel Yotebieng Montefiore Medical Center Albert Einstein College of Medicine Bronx, New York Denis Nash City University of New York Graduate School of Public Health and Health Policy New York, New York www.ca-iedea.org	Burundi Cameroon Rwanda Republic of the Congo Democratic Republic of the Congo

East Africa Kara Wools-Kaloustian Indiana University School of Medicine Indianapolis, Indiana Constantin Yiannoutsos Indiana University Richard M. Fairbanks School of Public Health Indianapolis, Indiana Aggrey Semeere Makerere University College of Health Sciences Kampala, Uganda www.iedea-ea.org	Kenya Tanzania Uganda
Southern Africa Matthias Egger University of Bern Bern, Switzerland Mary-Ann Davies University of Cape Town Cape Town, South Africa www.iedea-sa.org	Lesotho Malawi Mozambique South Africa Zambia Zimbabwe
West Africa Antoine Jaquet and Didier Ekouevi University of Bordeaux Inserm, French National Research Institute for Sustainable Development (IRD), UMR 1219 Bordeaux, France Ighovwerha Otofokun Emory University Atlanta, Georgia www.mereva.net/iedea	Benin Burkina Faso Cote d'Ivoire Ghana Mali Nigeria Senegal Togo

2. **Standard concept sheet template: available at** https://www.iedea.org/resources/administrative-resources/

3. **Fast-track concept sheet template: available at** https://www.iedea.org/resources/administrative-resources/

4. **Funding acknowledgements: available at** https://www.iedea.org/resources/administrative-resources/